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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/673,826

09/29/2003

John Voellmicke

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2220

27777 7590 11/29/2007  
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EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

11/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/673,826

Applicant(s)

VOELLMICKE, JOHN

Examiner

Anu Ramana

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 9/16/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 7, 9-14, 16-23, 27-29, 31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) 19, 20, 28, 29, 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7, 9-14, 16-18, 21-23 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/29/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 16, 2007 has been entered.

### ***Claim Objections***

Claim 27 is objected to because of the following informalities. It appears that the dependency of claim 27 should be changed to claim 23 from claim 1, due to the use of the term "advancing means." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

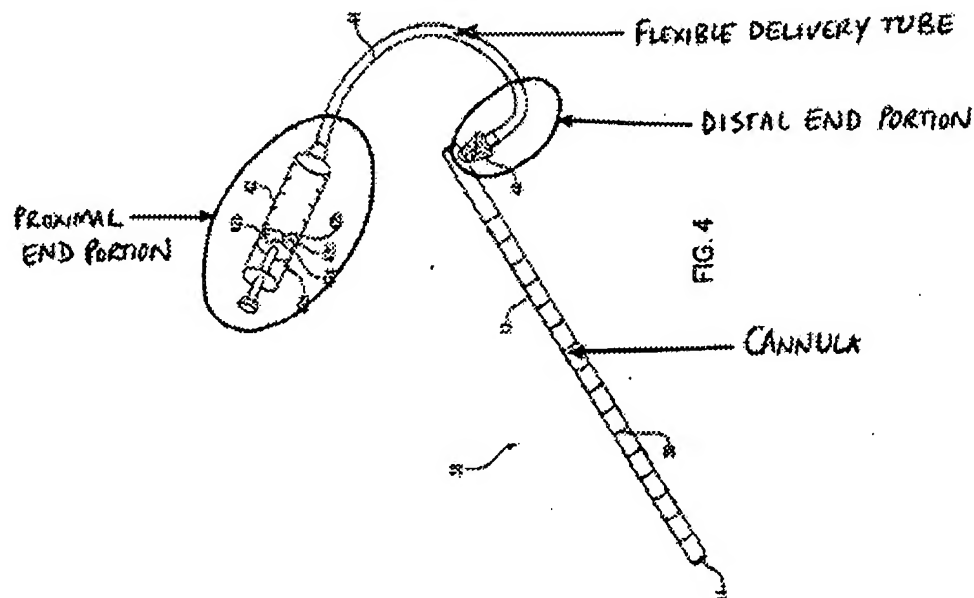
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 7, 9-14, 16-18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatnagar et al. (6,770,079) in view of Matukas (US 4,645,488).

Bhatnagar et al. disclose a syringe system or device for injecting bone cement including: a flexible delivery tube 44 having a proximal end portion 42; a plunger 42b; and a cannula 12 wherein movement of the plunger within the delivery tube can be automated by attachment to an electromechanical or pneumomechanical servo system

or "advancement means" (Fig. 4, col. 5, lines 45-67, col. 6 and col. 7, lines 1-56). See Fig. 4 marked up below to show elements of Applicant's invention.



Bhatnagar et al. disclose all elements of the claimed invention except for the proximal end portion 42 being flexible.

Matukas teaches a flexible syringe 10 with a flexible piston or plunger to reduce the frictional resistance between the material and the wall of the syringe or delivery tube (col. 2, lines 48-68, col. 3, lines 1-62 and col. 4, lines 15-26).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a flexible syringe with a flexible plunger, as taught by Matukas, in the Bhatnagar et al. system, to reduce the frictional resistance between the material being delivered and the wall of the syringe or delivery tube.

Regarding claim 3, although the combination of Bhatnagar et al. and Matukas does not disclose the syringe barrel being made of PEEK, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the syringe of PEEK, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use,

herein compatibility, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. See for example, US 7,011,649 (col. 3, lines 38-54).

Regarding claims 5 and 9-14, although the combination of Bhatnagar et al. and Matukas do not disclose the claimed ranges, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the device of the combination of Bhatnagar et al. and Matukas with the claimed ranges of dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claims 16 and 17, it is very well known to store bone cement at cold temperature to increase its shelf life. Thus, prior to use, the syringe would be filled from bone cement stored at a cold temperature. Although the combination of Bhatnagar et al. and Matukas does not disclose the claimed ranges of temperatures, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have filled the delivery tube in the device of the combination of Bhatnagar et al. and Matukas with bone cement having the claimed temperatures, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 1-3, 5, 7, 9-14, 16-18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatnagar et al. (US 6,770,079) in view of Clark (US 4,801,263).

Bhatnagar et al. disclose a syringe system or device for injecting bone cement including: a flexible delivery tube 44 having a proximal end portion 42; a plunger 42b; and a cannula 12; wherein movement of plunger 42b within the delivery tube can be automated by attachment to an electromechanical or pneumomechanical servo system or "advancement means" (Fig. 4, col. 5, lines 45-67, col. 6 and col. 7, lines 1-56).

Bhatnagar et al. disclose all elements of the claimed invention except for the flexible plunger having a distal end portion sized for slidable reception in the bore of the flexible delivery tube 44.

Clark teaches providing a flexible plunger extension or "distal end portion" to a plunger so that it can completely displace material through a curved nozzle or delivery tube (Fig. 7 and col. 5, lines 10-30).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a flexible distal end portion, as taught by Clark, to plunger 42b of the Bhatnagar et al. system, to completely displace material through curved delivery tube 44.

Regarding claim 3, although the combination of Bhatnagar et al. and Clark do not disclose the delivery tube 44 to be made of PEEK, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the syringe of PEEK, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein compatibility, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. See for example, US 7,011,649 (col. 3, lines 38-54).

Regarding claims 5 and 9-14, although the combination of Bhatnagar et al. and Clark do not disclose the claimed ranges, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the device of the combination of Bhatnagar et al. and Clark with the claimed ranges of dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claims 16 and 17, it is very well known to store bone cement at cold temperature to increase its shelf life. Thus, prior to use, the syringe would be filled from bone cement stored at a cold temperature. Although the combination of Bhatnagar et al. and Clark do not disclose the claimed ranges of temperatures, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

have filled the delivery tube in the device of the combination of Bhatnagar et al. and Clark with bone cement having the claimed temperatures, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatnagar et al. (US 6,770,079) and Matukas (US 4,645,488) further in view of Sams (US 4,865,591).

The combination of Bhatnagar et al. and Matukas discloses all elements of the claimed invention except for: (1) the plunger having ratchet teeth or a textured surface; (2) a pawl adapted to compliment the ratchet teeth of the plunger; and (3) a hand-held gun.

Sams teaches providing ratchet teeth on the plunger of a syringe and a complementary pawl in a hand-held gun to dispense fluid from the syringe (Figs. 2 and 3, col. 4, lines 59-68 and col. 5, lines 1-28).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided ratchet teeth on the plunger in the device of the combination of Bhatnagar et al. and Matukas, as taught by Sams, to dispense accurately controlled but variable doses of fluid.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatnagar et al. (US 6,770,079) and Clark (US 4,801,263) further in view of Sams (US 4,865,591).

The combination of Bhatnagar et al. and Clark discloses all elements of the claimed invention except for: (1) the plunger having ratchet teeth or a textured surface; (2) a pawl adapted to compliment the ratchet teeth of the plunger; and (3) a hand-held gun.

Sams teaches providing ratchet teeth on the plunger of a syringe and a complementary pawl in a hand-held gun to dispense fluid from the syringe (Figs. 2 and 3, col. 4, lines 59-68 and col. 5, lines 1-28).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided ratchet teeth on the plunger in the device of the combination of Bhatnagar et al. and Clark, as taught by Sams, to dispense accurately controlled but variable doses of fluid.

### ***Response to Arguments***

Applicant's arguments submitted under "REMARKS" in the response filed on September 16, 2007 have been fully considered.

Applicant's arguments with respect to the rejections under 35 USC 103(a) over Bhatnagar et al. (US 2002/0049449 or US 6,770,079) in view of Matukas et al. (US 4,645,488) are not persuasive because they are not directed to claim limitations. Claim 1 of Applicant's invention only requires a portion of the delivery tube to be flexible. It is the Examiner's position that neither the proximal end portion nor the distal end portion of the delivery tube need to be flexible. The Examiner has clarified syringe 42 of Bhatnagar et al. to be "the proximal end portion" of flexible delivery tube 44 in this action.

Matukas teaches a plunger 14 made of nylon or a "flexible material." It is the Examiner's position that when a plunger or rod is made of nylon, it is capable of being bent or flexed, i.e. it is flexible (Source: The American Heritage® Dictionary of the English Language: Fourth Edition. 2000.). For example, Hayakawa et al. (see col. 7, lines 51-62) discloses a push rod or plunger 31 made of a flexible material such as nylon.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
November 24, 2007

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